

SAFETY DATA SHEETS

This SDS packet was issued with item:

075908553

N/A

IDENTITYTrade Name: *Pulpdent Snoop Caries Detecting Dye*

Code: SNOOP

Chemical Description: Colorant in propylene glycol and water solution.

Product Use: Dental caries indicator

SECTION I*Pulpdent Corporation**Phone Numbers*

80 Oakland Street

24 Hour Emergency: 1-800-535-5053

Watertown, MA 02472 USA

Customer Service: 1-800-343-4342/1-617-926-6666

Date prepared: September 1, 2008

SECTION II - INGREDIENTS:

| <i>Ingredients</i> | <i>CAS RN</i> | <i>%</i> |
|-----------------------|---------------|----------|
| Water | 7732-18-5 | 47.0 |
| Propylene glycol, USP | 57-55-6 | 47.0 |
| Emulsifier | ----- | < 5.0 |
| Colorant | ----- | < 1.0 |

DOT/ WHMIS HAZARD CLASSIFICATION: Not regulated

NFPA HMIS RATING: HEALTH: 0 FLAMMABILITY: 0 REACTIVITY: 0

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

| | | |
|-------------------------------|------------------------|-------------------------------|
| Boiling point: 220° F | Specific gravity: 1.06 | Freezing point: -20° F |
| Solubility in water: Complete | Odor: Odorless | Odor threshold: Not available |
| Color: Very dark blue | | |

SECTION IV - FIRE AND EXPLOSION HAZARD

Flash point: Not applicable Auto-ignition Temperature: Not applicable

Flammable limits: Not applicable Hazardous Combustion Products: None

Extinguishing Media: Use whatever is appropriate for surrounding fire.

Special Fire Fighting Procedures: None other than that required for safe practice.

Unusual Fire and Exposure Hazards: None known.

SECTION V - REACTIVITY DATA

Stability: Stable Conditions to avoid: None

Incompatibility: None Hazardous Decomposition Products: None

Hazardous Polymerization: No Conditions to avoid: None

SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: None expected under normal conditions of use.

Route of Exposure**Signs and Symptoms**

Inhalation

None

Eye contact

May cause irritation on contact with eyes.

Skin absorption

None

Skin contact

Material is a dye that will stain skin and soft tissue.

Ingestion

None expected under normal conditions of use.

Summary of Chronic Hazards: None expected under normal conditions of clinical practice.
Carcinogenicity Not known to be a carcinogen.
Teratogenicity, Mutagenicity, Reproductive toxicity: None known

Emergency First Aid Procedures:

Inhalation Remove patient to fresh air. Seek medical advice
Eye contact Rinse eyes under running water for 15+ minutes.
Skin contact Wash with soap and water.
Ingestion Seek medical advice.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING AND USE


Handling and Storage Precautions: Store tightly capped in original container at cool room temperature.
Release or spill: Wear gloves, lab coat and safety glasses. Wipe up with absorbent material, such as paper towels or cloth. Wash area of spill with detergent and water as soon as possible after spill.
Waste Disposal Method: Follow all government regulations.
Other Precautions: Material stains skin, clothing and carpeting. Avoid spills. Wash hands after use. Wash clothing and carpeting with detergent and water as soon as possible.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: Not necessary under normal conditions of use.
Ventilation: No special ventilation required under normal conditions of use.
Protective Gloves: Chemically impervious gloves to prevent staining of skin.
Eye Protection: Safety glasses are recommended under normal conditions of use.
Protective Clothing/Equipment: Emergency eye wash fountain should be close by and maintained. Wear lab coat and/or apron to protect clothing from splashed dye.
Work / Hygienic Practices: Wash hands after use

The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.

Safety Data SheetTrade Name: **SNOOP Caries Detecting Dye**

| 1.0 Commercial Product Name and Supplier | | | | | | | | | | | | | |
|--|--|-------------------------|------------------------|-------------------------|----------------|---|------|---------|---|------|-----------------|---|------|
| 1.1 Commercial product name / designation | Snoop Caries Detecting Dye | | | | | | | | | | | | |
| 1.2 Application / Use | Dental material for use by dental professionals. | | | | | | | | | | | | |
| 1.2.2 SIC | 851 Human health activity | | | | | | | | | | | | |
| 1.2.3 Use Category | 55 | | | | | | | | | | | | |
| 1.3 Manufacturer | <i>Pulpdent Corporation</i> 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA | | | | | | | | | | | | |
| | Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com | | | | | | | | | | | | |
| 1.4 Emergency Telephone Number | 1-800-535-5053 (24 Hour / USA) | | | | | | | | | | | | |
| 1.5 Authorized European Representative | Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom | | | | | | | | | | | | |
| 2.0 Hazards Identification | | | | | | | | | | | | | |
| 2.1 Classification | | | | | | | | | | | | | |
| 2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP] | <table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></th> </tr> </thead> <tbody> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td>STOT SE</td> <td>3</td> <td>H335</td> </tr> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> </tbody> </table> | <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | Eye irritation | 2 | H319 | STOT SE | 3 | H335 | Skin irritation | 2 | H315 |
| <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | | | | | | | | | | | |
| Eye irritation | 2 | H319 | | | | | | | | | | | |
| STOT SE | 3 | H335 | | | | | | | | | | | |
| Skin irritation | 2 | H315 | | | | | | | | | | | |
| 2.1.2 Classification according to Directive 67/548/EEC | Irritant (Xi) R36 / 37 / 38 (See SECTION 16 for full text of risk phrases) | | | | | | | | | | | | |
| 2.2 GHS Label Elements | | | | | | | | | | | | | |
| Hazard Pictograms |  | | | | | | | | | | | | |
| Signal Word: WARNING | | | | | | | | | | | | | |
| Restricted to use by dental professional only | | | | | | | | | | | | | |
| Hazard Statements: | | | | | | | | | | | | | |
| H319: Causes serious eye irritation. Category 2. | | | | | | | | | | | | | |
| H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. | | | | | | | | | | | | | |
| H315: Causes skin irritation. Category 2. | | | | | | | | | | | | | |
| Precautionary Statements: | | | | | | | | | | | | | |
| P261: Avoid breathing fumes. | | | | | | | | | | | | | |
| P280: Wear protective gloves / clothing and eye protection. | | | | | | | | | | | | | |
| P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. | | | | | | | | | | | | | |
| P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. | | | | | | | | | | | | | |
| P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water. | | | | | | | | | | | | | |
| 3.0 Composition | | | | | | | | | | | | | |
| 3.1 Chemical characterization of the preparation: | Mixture of propylene glycol, water, colorant and emulsifier | | | | | | | | | | | | |

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3.2 Hazardous ingredients

| CAS Number | Name of the Ingredient | Concentration | Classification per 67/548/EEC | Classification per Regulation (EC) No.1272/2008 (CLP). |
|------------|------------------------|---------------|--------------------------------|--|
| 57-55-6 | Propylene glycol, USP | 49.5% | Irritant (Xi) R36 | Eye irritation, Category 2 |
| 7732-18-5 | Water | 49.5% | ---- | ----- |
| ----- | Colorant | < 1.0% | Irritant (Xi) R36 / 37 / 38 | Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2. |
| ----- | Emulsifier | < 5.0 % | Irritant (Xi) R36 / 37 / 38 | Eye irritation, Category 2 STOT SE, Category 3 Skin irritation Category 2. |

4.0 First Aid Measures

| | | |
|-----|----------------------------------|---|
| 4.1 | General Information | Not hazardous to health or environment. Snoop is a dye that will stain soft tissue and absorbent materials. May cause slight, temporary eye irritation. Corneal injury is unlikely. May cause mild skin or respiratory irritation. Show this safety data sheet to medical personnel. Seek medical attention in case of uncertainty. |
| 4.2 | Eye Contact | Keep eyelids apart, flush with running water for 15+ minutes. Remove contact lenses after several minutes. Get medical advice or attention as indicated. |
| 4.3 | Skin Contact | Remove contaminated clothing. Immediately wash with soap and running water. Get medical attention for persistent irritation. |
| 4.4 | Ingestion | Rinse mouth with water to minimize staining of soft tissue. No emergency medical treatment necessary. |
| 4.5 | Inhalation | Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention. |
| 4.6 | Precautions for first responders | Wear safety glasses and gloves. |
| 4.7 | Information for physicians | |
| | Symptoms | Contact with material may cause mild irritation in eyes, respiratory system or on skin. Skin and soft tissue may be stained. |
| | Hazards | May cause irritation. |
| | Treatment | Same as above under First Aid |

5.0 Fire Fighting Measures

| | | |
|-----|--|---|
| 5.1 | Suitable extinguishing media | Decision should be based on surrounding fire. |
| 5.2 | Extinguishing media to avoid | Decision should be based on surrounding fire. |
| 5.3 | Special exposure hazards in a fire | None |
| 5.4 | Special protective equipment for fire-fighters | None |

6.0 Accidental Release Measures

| | | |
|-----|-----------------------|---|
| 6.1 | Personal precautions. | Material will stain skin and clothing. Wear gloves, lab coat and/or apron and safety glasses. |
|-----|-----------------------|---|

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| | | |
|---------|--|--|
| 6.2 | Environmental precautions | Not hazardous to environment. Follow all government regulations. |
| 6.3 | Method for clean up | Absorb or wipe up spill with paper towels or disposable cloths. Collect for disposal in a drip-proof plastic bag or container to prevent further staining of surroundings. Wash area of spill promptly with alcohol or soap and water, though discoloration of spill area may persist. |
| 7.0 | Handling and Storage | |
| 7.1 | Handling | Medical device for use only by trained dental professionals. Follow good hygiene practices. Re-cap container immediately to prevent spills. |
| 7.2 | Storage | Store tightly capped at cool room temperature. Avoid temperature extremes (>27°C/80°F, <5°C/40°F). Shelf life for properly stored, unopened product is two years from date of manufacture. |
| 7.3 | Specific uses | Dental material |
| 8.0 | Exposure Controls / Personal Protection | |
| 8.1 | Exposure limit values | Not established |
| 8.2 | Exposure controls | |
| 8.2.1 | Occupational exposure controls | No special equipment or ventilation required under normal conditions of use in dental practice. |
| 8.2.1.1 | Respiratory protection | No special requirements under normal conditions of use. |
| 8.2.1.2 | Hand protection | No special requirements other than surgical gloves. |
| 8.2.1.3 | Eye protection | No special requirements other than safety glasses. |
| 8.2.1.4 | Skin protection | No special requirements other than good hygiene and safety practices to prevent contact with skin and subsequent staining. |
| 8.2.1.5 | Other controls | Emergency eye wash fountain should be close by. Wash hands after use. Do not eat, drink or smoke. |
| 8.2.2 | Environmental exposure controls | Follow all government regulations. |
| 9.0 | Physical and Chemical Properties | |
| 9.1 | Characteristics | |
| 9.1.1 | Appearance / Color / Physical state | Very dark blue liquid |
| 9.1.2 | Odor | None |
| 9.2 | Important health, safety and environmental information | |
| 9.2.1 | pH | Not determined |
| 9.2.2 | Boiling point | Boiling Point: 220°F / 105°C |
| 9.2.3 | Flash point | Not applicable |
| 9.2.4 | Ignition temperature | Not applicable |
| 9.2.5 | Explosive properties | Not applicable |
| 9.2.6 | Odor threshold | Not applicable |
| 9.2.7 | Vapor pressure | Not determined |
| 9.2.8 | Specific gravity | 1.060 |

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|--------|--|--|
| 9.2.9 | Solubility in water | Complete |
| 9.2.10 | Partition coefficient | Not determined |
| 9.2.11 | Viscosity | Not determined |
| 9.2.12 | Vapor density | Not determined |
| 9.2.13 | Evaporation rate | Not determined |
| 10.0 | Stability and reactivity | |
| 10.1 | Conditions to avoid | None. |
| 10.2 | Materials to avoid | None |
| 10.3 | Hazardous decomposition products | None |
| 10.4 | Further information | None |
| 11.0 | Toxicological information | |
| 11.1 | Acute toxicity | Not toxic. Minimal health hazard under normal conditions of use. |
| 11.2 | Irritation and corrosiveness | May cause irritation/redness of eyes, skin or respiratory system. |
| 11.3 | Sensitization | Not applicable. |
| 11.4 | Sub-acute, sub-chronic and prolonged toxicity | Not toxic |
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | Not carcinogenic. No mutagenicity/ reproductive toxicity known. |
| 11.6 | Empirical data | None available |
| 11.7 | Clinical experience | Snoop has been sold to and used by dentists all over the world for about 15 years with no reported problems. |
| 12.0 | Ecological Information | |
| 12.1 | Ecotoxicity | Not toxic. Follow good work practices and government regulations. |
| 13.0 | Disposal Considerations | |
| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
| 14.0 | Transport Information | |
| 14.1 | UN Number | Not regulated |
| 14.2 | Technical name | Not applicable |
| 14.3 | Packing group | Not applicable |
| 14.4 | IATA class | Not applicable |
| 15.0 | Regulatory Information | |
| 15.1 | EU | Class IIa medical device under MDD 93/42/EEC. |
| 15.2 | US FDA | Class II medical device |
| 15.3 | Health Canada | Class II medical device |

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| | | |
|------|---|--|
| 16.0 | Other information | |
| 16.1 | List of relevant R phrases | R36/37/38: Irritating to eyes, skin, and respiratory system. |
| 16.2 | Hazard Statements | H319: Causes serious eye irritation. Category 2. H335: Specific Target Organ Toxicity (STOT), single exposure, respiratory tract, Category 3: May cause respiratory irritation. H315: Causes skin irritation. Category 2. |
| 16.3 | Precautionary Statements | P261: Avoid breathing fumes. P280: Wear protective gloves / clothing and eye protection. P304+P340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P303+P361+P353: If on skin or hair, remove contaminated clothing. Rinse skin with water. |
| 16.4 | Restrictions on use | Pulpdent dental materials, such as Snoop are to be sold to and used by dental professionals only. |
| 16.5 | Further information | The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate. |
| 16.6 | Sources of key data | National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency |
| 16.7 | Information which has been added, deleted or revised. | This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified. |